

Remarks

Upon entry of the foregoing amendments, claims 1 and 3 to 19 will be pending. Claims 16 to 18 have been amended, without prejudice, to insert generic terminology where trademarks appear and to define abbreviated terms. Claims 9 to 19 have been amended, without prejudice, to place same in method claim format. Claims 2 and 20 to 32 have been cancelled, without prejudice. The specification has been amended to insert generic terminology where trademarks appear. No new matter has been introduced.

Discussion of the Rejections under 35 U.S.C. § 112

Claims 2, 16 to 18 and 21 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter which applicants regard as the invention. Although applicants do not agree, it is respectfully submitted that this rejection is moot with regard to claims 16 to 18 in view of the amendments thereto and moot with regard to claims 2 and 21 in view of the cancellation of such claims.

In particular, the Action rejects claims 2 and 21 as the term “late-onset” is not defined. Although applicants do not agree, it is respectfully submitted that this rejection is moot in view of the cancellation of claims 2 and 21.

The Action rejects claim 16 as the terms “SSRI” and “MAO” are not defined therein. Claim 16 has been amended to incorporate such definitions.

Further, the Action rejects claims 17 and 18 as the trademarks therein are not accompanied by the generic terminology. Claims 17 and 18 have been amended to incorporate such terminology.

Discussion of the Rejection under 35 U.S.C. § 102(b)

Claims 9 to 32 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent Application Publication No. 2005/0143350 to Seed et al. (“Seed”). Applicants respectfully traverse this rejection with regard to amended method of treatment claims 9 to 19 because Seed does not disclose each and every element of Applicant’s claimed inventions.

For a reference to anticipate a claim under 35 U.S.C. § 102, “the identical invention must be shown in as complete detail as is contained in the ... claim” (*Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989)). Further, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” (*Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic (*In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)). In particular, the examiner must provide a

basis in fact and/or technical reasoning to reasonably support a determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art (*Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)).

Applicants' claims define "a method of treating vascular depression comprising administering to a subject in need of such treatment a pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and a therapeutically effective amount of: 1) a cholinesterase inhibitor; and 2) an anti-depressant ..." (see e.g. claim 9).

In contrast, Seed teaches methods of treating obesity comprising administering at least one cholinesterase inhibitor in combination with at least one anti-depressant (see Seed at [0005]). Seed discloses that cholinesterase inhibitors are also useful for treating diseases such as Alzheimer's and that anti-depressants are, as named, useful for treating depression (see Seed at [0028]). Seed does not teach or suggest the treatment of vascular depression, or the use of a combination of cholinesterase inhibitors and anti-depressants to treat vascular depression. Applicants respectfully submit that the present claims are thus patentable over Seed at least for the above reason. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Discussion of the Rejections under 35 U.S.C. § 103(a)

Claims 9 to 19 and 32 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Seed in view of U.S. Patent Application Publication No. 2002/0192243 to Hsu et al. ("Hsu"). Although Applicants do not concede that Seed can be combined with Hsu, the combination of Seed and Hsu (*arguendo*) does not produce the presently claimed invention.

"A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field" (*In re Kotzab*, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000)). "The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time" (*In re Dembiczaik*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) (quoting *Interconnect Planning Corp. v. Feil*, 227 U.S.P.Q. 543, 547 (Fed. Cir. 1985)). To establish a *prima facie* case of obviousness, "the examiner must show reasons that the skilled artisan, confronted with the same problem as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed" (*In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998)).

As noted above, Applicants' claims define methods of treating vascular depression using the combination of a cholinesterase inhibitor and an antidepressant. Seed does not disclose the treatment of vascular depression, or the use of a combination of cholinesterase inhibitors and anti-depressants to treat vascular depression. The Action then combines Seed with Hsu, for the mere purpose of "demonstrat[ing] administration of cholinesterase inhibitor by transdermal

patch" (Action at 5). Hsu teaches methods of enhancing permeability of skin to drugs used to treat Alzheimer's disease, which include cholinesterase inhibitors (see Hsu at [0033]). Hsu, like Seed, does not disclose the treatment of vascular depression, or the use of a combination of cholinesterase inhibitors and anti-depressants to treat vascular depression. The Action does not provide any evidence to show why one of ordinary skill in the art, when presented with the disclosures of Seed and Hsu at the time of the present invention, would be motivated to use the combination of cholinesterase inhibitors and anti-depressants to treat vascular depression, as defined by applicants' claimed invention. Claims 9 to 19 are thus patentable in view of the combination of Seed and Hsu. Reconsideration and withdrawal of the rejection are requested respectfully for at least this reason.

Claims 1 to 32 are rejected as under 35 U.S.C. §103(a) as allegedly unpatentable over Roman et al., *The Lancet Neurology*, 1:426-436 (2002) ("Roman") in view of Seed and Hsu. Although Applicants do not concede that Roman can be combined with either Seed or Hsu, the combination of Roman, Seed and Hsu (*arguendo*) does not produce the presently claimed invention.

Applicants' claims define "a method of treating vascular depression comprising administering to a subject in need of such treatment a therapeutically effective amount of a cholinesterase inhibitor ..." (see, e.g., claim 1). Applicants' claims further define "a method of treating vascular depression comprising administering to a subject in need of such treatment a pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and a therapeutically effective amount of: 1) a cholinesterase inhibitor; and 2) an anti-depressant ..." (see e.g. claim 9).

Roman, in contrast, teaches that vascular dementia may potentially be treated using cholinesterase inhibitors (see Roman at page 434, paragraphs 1, 2). Roman also discloses that vascular dementia is associated, in one clinical manifestation, with mood disorders which may include vascular depression (see Roman at page 431, Col. 1, paragraphs 2, 6). Roman therefore discloses that although vascular depression may be associated with vascular dementia, vascular depression is not necessarily present in conjunction with vascular dementia. Further, vascular depression is recognized in the art as a separate disease. Roman's disclosure of vascular dementia treatment is thus not a teaching of vascular depression treatment. The combination of Roman with Seed and Hsu, which also do not disclose the treatment of vascular depression or vascular dementia, still does not provide any evidence to show why one of ordinary skill in the art, when presented with the disclosures of Roman, Seed and Hsu at the time of the present invention, would be motivated to use the combination of cholinesterase inhibitors and anti-depressants to treat vascular depression, as defined by applicants' claimed invention. Claims 1 and 3 to 19 are thus patentable in view of the combination of Roman, Seed and Hsu. Reconsideration and withdrawal of the rejection are requested respectfully for at least this reason.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Action of record. If there are any issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney.

It is hereby requested that the term to respond to the Action of April 10, 2008 be extended pursuant to 37 C.F.R. § 1.136(a) for three (3) months, from July 10, 2008 to October 10, 2008. The Commissioner is hereby authorized to charge any fees required to Deposit Account No. **19-0134** in the name of Novartis.

Respectfully submitted,

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